

REMARKS

The pending Office Action addresses and rejects claims 1-26. Applicants respectfully request consideration in view of the amendments and remarks submitted herein.

Amendments to the Claims

Claim 1 is amended to include the limitations of claim 5, which is now cancelled.

Claim 21 is amended to clarify that the distal portion is adapted to retract tissue when the at least one tissue retractor and guide device is mated to the spinal fixation plate. Support for this amendment can be found through the specification, for example, at page 6, lines 18-25.

Claims 22, 23, and 25 are amended to depend from claim 21.

No new matter is added.

Claim Objections

The Examiner rejects claims 22 and 23 as depending from claim 20, rather than kit claim 21. As noted above, claims 22 and 23, as well as claim 25, are amended to depend from claim 21, rather than claim 20, thereby obviating the basis for this rejection.

Objection to the Drawings

The Examiner objects to the drawings as failing to show a clamp member and post as recited in claims 16 and 17. Applicants respectfully disagree with the Examiner's request for drawings illustrating a clamp and a post, as drawings showing such features are not necessary. 35 U.S.C. §113, first sentence, states that an "applicant shall furnish a drawing where necessary for the understanding of the subject matter sought to be patented." Clamps and posts for mating a device to a support are well known in the art, and no person having ordinary skill in the art needs to see a drawing of a clamp or post to understand the subject matter being claimed. Accordingly, drawings showing such features are not necessary for the understanding of the invention. Reconsideration and withdrawal of this requirement is therefore respectfully requested.

Objection to the Specification

The Examiner requests that all uses of the term BOOKWALTER™ in the specification be capitalized and contain the TM symbol. Applicants have amended the specification to correct this error, thereby obviating the basis for this objection.

Claim Rejections Pursuant to 35 U.S.C. §102

U.S. Patent No. 3,626,471 of Florin

Claims 1-4, 6-11, 14, and 16-20 stand rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,626,471 of Florin. The Examiner argues that Florin discloses a device (10) having an elongate member with a planar surface (11) capable of retracting tissue, and guide members (13, 14) with lumens (15, 16) therethrough.

(a) Claims 1-4, 6-11, 14, and 16-17

As indicated above, independent claim 1 is amended to include the limitations of claim 5, thereby obviating the basis for this rejection with regard to claims 1-4, 6-11, 14, and 16-17.

(b) Claims 18-20

Independent claim 18 recites a tissue retractor and drill guide kit that includes at least one tissue retractor and guide device having a guide member with at least one barrel defining a lumen for receiving a tool, and an elongate member having a proximal handle portion and a distal tissue-retracting portion. At least one of the guide member and the elongate member is adapted to couple to a spinal implant. The kit also includes a cross member that is adapted to removably connect two tissue retractor and guide devices.

First, Florin does not teach or even suggest a retractor and guide device having a guide member or an elongate member that is adapted to couple to a spinal implant. Florin merely teaches a brain retractor having a blade with suction tubes disposed thereon. There is nothing on the device that allows it to couple to a spinal implant, as required by claim 18. Florin therefore cannot

anticipate claim 18, as it does not disclose any feature that is inherently capable of performing the claimed function.

Florin also fails to teach or even suggest a cross member that is adapted to removably connect two tissue retractor and guide devices. The Examiner argues that fiber optic element 21 could be considered to be a cross-connector. The fiber optic element 21 does not include anything that would allow it to function as a cross-connector for mating two tissue retractor and guide devices. It is merely mated to the blade of the device. There are no mating elements on the fiber optic element, and there is nothing in Florin to indicate that the fiber optic element can removably mate to another retractor device. Claim 18 specifically requires a cross-connector that is adapted to removably connect two tissue retractor and guide devices, and Florin does not include anything that is capable of performing the claimed function of removably connecting two devices. Florin therefore cannot anticipate claim 18.

Claim 18, as well as claims 19-20 which depend therefrom, therefore distinguish over Florin and represent allowable subject matter.

U.S. Patent No. 5,676,666 of Oxland et al.

Claims 1-4, 6-14, and 16-24 stand rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,676,666 of Oxland et al. (“Oxland”). The Examiner argues that Figure 1 of Oxland illustrates a device having an elongate member (62) with planar retracting surfaces (72, 74), and removable guide members (80, 82) with lumens therethrough.

(a) Claims 1-4, 6-14, and 16-17

As indicated above, independent claim 1 is amended to include the limitations of claim 5, thereby obviating the basis for this rejection with regard to claims 1-4, 6-14, and 16-17.

(b) Claims 18-20

As previously discussed, independent claim 18 recites a tissue retractor and drill guide kit that includes at least one tissue retractor and guide device and a cross member that is adapted to removably connect two tissue retractor and guide devices. Oxland is deficient for several reasons.

First, Oxland does not teach or even suggest an elongate member having a distal, tissue-retracting portion, as required by claim 18. The distal end of the elongate member includes two blades (68, 70) that pivot relate to one another. Each blade is mated to a guide head (72, 74) that slidably receives a guide cylinder (80, 82). Because the distal end of each blade is mated to and disposed within a cut-out formed in a guide head, as shown in Figure 1A of Oxland, the blades cannot be used to retract tissue, and thus they cannot form tissue-retracting portions.

Oxland also fails to teach or even suggest a cross member that is adapted to connect two tissue retractor and guide devices. The Examiner argues that the hinge between the two blades constitutes a cross member. This is incorrect. The hinge does not removably mate two retracting devices, it only mates two blades of one device. There is nothing in Oxford to indicate that the hinge can removably mate to another device, and in fact there is nothing that even indicates that the hinge is removably mated to the blades.

Oxland therefore cannot anticipate claim 18, and thus claim 18, as well as claims 19-20 which depend therefrom, distinguish over Oxland.

(c) *Claims 21-24*

Independent claim 21 recites a spinal fixation kit that includes a spinal fixation plate having superior and inferior portions with at least one bore formed therein, and at least one tissue retractor and guide device having an elongate member with a distal portion that is adapted to retract tissue when the at least one tissue retractor and guide device is mated to the spinal fixation plate, and a guide member mated to the distal portion and having at least one lumen for receiving a tool.

Oxland discloses a spinal plate and an installation device for installing the plate, however the installation device does not include a guide member with a distal end that is adapted to retract tissue when it is mated to the spinal fixation plate. As shown in Figure 1 of Oxland, each guide head (72, 74) includes a lip (76, 78) formed thereon. The lips are configured to grasp a plate therebetween. When mated, as shown in Figures 5 and 6 of Oxland, the installation tool extends from a superior surface of the plate. It does not include a distal end that could be used to retract tissue. In fact, the mating connection between the installation tool and the plate would clearly prevent the tool from being used to retract tissue.

Claim 21 therefore distinguishes over Oxland and represents allowable subject matter. Claims 22-24 are allowable at least because they depend from allowable claim 21.

Claim Rejections Pursuant to 35 U.S.C. §103

(a) Claim 5

Claim 5, which is now amended into claim 1, is rejected pursuant to 35 U.S.C. §103(a) as being obvious over Oxland in view of U.S. Patent No. 4,686,972 of Kurland. The Examiner argues that Oxland discloses the claimed invention, but admits that Oxland fails to teach concave end portions. Thus, the Examiner relies on Kurland to disclose a drill guide (10) having concave ends (6) to facilitate proper seating on the drilling target. The Examiner submits that it would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the device of Oxland with a concave end as taught by Kurland “in order to facilitate proper seating on a drilling target and improve the procedure.” Applicants respectfully disagree.

It would not have been obvious to modify Oxland to include a concave distal surface as taught by Kurland because such a modification would render the Kurland device inoperative for its intended use. The installation tool of Oxland is specifically configured to engage and mate to a plate, as shown in Figures 5 and 6 of Oxland. No part of the tool is positioned against bone, except potentially the lips that engage the plate. If the distal end of the tool were made concave it would not mate with the plate, as required by Oxland.

Applicants further note that the Examiner’s suggested motivation to modify the references is misplaced. No person having ordinary skill in the art would be motivated to modify the distal end of a tool that is used to engage a plate in order to facilitate proper seating on a drilling target, e.g., bone. The tool is not placed against bone, so there is no reason to facilitate proper seating.

Applicants further note that claim 1 requires the distal-most surface of the elongate member to be substantially concave. The blades of the installation tool of Oxland are the only thing that can be considered to be an elongate member, and the blades are merely housed within and mated to guide cylinders. There is no reason to provide concave mating surfaces of blades that terminate inside a housing.

Claim 1 therefore distinguishes over Oxland and Kurland, taken alone or combined, and represents allowable subject matter.

(b) *Claims 15, 25, and 26*

The Examiner rejects claims 15, 25, and 26 pursuant to 35 U.S.C. §103(a) as being obvious over Oxland. Claim 15 depends from claim 1, and claims 25 and 26 depend from claim 21. Thus, for the same reasons previously discussed with respect to claims 1 and 21, claims 15, 25, and 26 distinguish over Oxland and represent allowable subject matter.

Conclusion

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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